Department of Justice

STATEMENT OF

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BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

FOR A HEARING ENTITLED

"CURBING PRESCRIPTION DRUG ABUSE IN MEDICARE"

PRESENTED ON

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Testimony of Deputy Assistant Administrator Joseph T. Rannazzisi Office of Diversion Control, Drug Enforcement Administration before the United States Senate **Committee on Homeland Security and Governmental Affairs** Monday, June 24, 2013

Introduction

Chairman Carper, Ranking Member Coburn, and distinguished Members of the Committee on Homeland Security and Governmental Affairs, on behalf of Drug Enforcement Administrator Michele M. Leonhart and the men and women of the Drug Enforcement Administration (DEA), I want to thank you for the opportunity to discuss the epidemic of pharmaceutical controlled substance abuse and the diversion of controlled substance pharmaceuticals.

Abuse of Controlled Substance Pharmaceuticals

The abuse of prescription drugs continues to plague the nation at an alarming rate, crossing all age, gender, racial and socioeconomic boundaries. Studies show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the adverse consequences associated with such actions. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2011 National Survey on Drug Use and Health (NSDUH)—the most recent NSDUH—the number and percentage of persons aged 12 or older who were current (past month) nonmedical users of psychotherapeutic drugs in 2011 (6.1 million or 2.4 percent) were lower than the estimates in 2010 (7.0 million or 2.7 percent) and 2009 (7.0 million or 2.8 percent). Psychotherapeutic drugs include prescription-type pain relievers, tranquilizers, stimulants, or sedatives, but not over-the-counter substances. Although the most recent statistics reveal a slight downward trend, the abuse of pharmaceutical controlled substances is still alarming.

An estimated 8.0 million people aged 12 or older (3.1 percent of the population) were current users of illicit drugs other than marijuana in 2011; the majority of these users (6.1 million persons, or 2.4 percent of the population) were non-medical users of psychotherapeutic drugs. In 2011, 2.3 million persons aged 12 or older used psychotherapeutic drugs non-medically for the first time within the previous year, which averages to around 6,400 initiates per day. The number of new non-medical users of psychotherapeutic drugs in 2011 was similar to the 2010 estimate (2.4 million), but lower than the 2004 estimate (2.8 million). Of the total number of non-medical users of psychotherapeutic drugs in 2011, the number of new non-medical users of pain relievers (1.9 million) was lower than the numbers in 2002 through 2005 and in 2008 and 2009 (ranging from 2.2 million to 2.5 million). In 2011, the number of initiates of other psychotherapeutic drugs was 1.2 million for tranquilizers, 670,000 for stimulants, and 159,000 for sedatives. The non-medical use of prescription drugs is the second-leading category of illicit drug use among Americans 12 and older—second only to

1 Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

marijuana use.² Among this population, the number of new initiates who used narcotic pain relievers is second only to the number of new initiates who used marijuana.³

This data is particularly disturbing because prescription opiate abuse by teens and young adults can lead to heroin abuse. DEA intelligence has shown that the "street" cost of prescription opiates - as high as \$80.00 per tablet or more in the case of OxyContin 80 mg, and \$30.00 to \$40.00 per tablet for 30 mg oxycodone single entity immediate release - makes it difficult for teens and young adults to purchase the drugs to continue use in support of their addiction. As a result, intelligence indicates that some users of prescription opiates turn to heroin, a much cheaper opiate that provides a similar "high" and keeps the drug seeker/abuser from experiencing painful withdrawal symptoms. This cycle has been confirmed by police agencies throughout the country, who are now reporting an increase in heroin use by teens and young adults who began their cycle of abuse with prescription opiates. In 2011, 178,000 persons aged 12 or older used heroin for the first time within the previous 12 months. Although this number was similar to the estimates in 2010(142,000) and 2009 (187,000), the 2011 estimate was higher than the estimates during 2005 to 2007 (ranging from 90,000 to 108,000 per year). A special analysis by NSDUH researchers indicates that 81 percent of heroin initiates in 2008-2010 had previously used pain relievers non-medically. Among recent initiates aged 12 to 49, the average age for first-time heroin use was 22.1 years, which was similar to the 2010 estimate (21.4 years).⁵

This cycle of abuse can be traced to the mistaken belief among teens and young adults that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana, and methamphetamine, combined with, at least initially, easy access to prescription medications. The 2012 Partnership Attitude Tracking Study (PATS) noted that 43 percent of teenagers believe that prescription medications are "easier to obtain" than illegal drugs. Because prescription medications are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacists, teens and young adults often have a false sense of security regarding these potent and dangerous medications. In fact, according to the same 2012 PATS, 27 percent of teens mistakenly believe that misusing or abusing prescription drugs is "safer" than using street drugs. Other key points revealed in the 2012 PATS are that 1 in 4 teens (24 percent) admitted to having misused or abused a prescription drug at least once in their lifetime; 33 percent of teens said they believe "it's okay to use prescription drugs that were not prescribed to them to deal with an injury, illness, or physical pains;" and 23 percent of teens said their parents don't care as much if they are caught using prescription drugs without a doctor's prescription, compared to getting caught with illegal drugs. Sixteen percent of teens said they discussed the misuse or abuse of prescription pain relievers with their parents.⁹

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² Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

³ Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

⁴ Gfroerer, Joe and Muhuri, Pradip. Associations between nonmedical pain reliever use and heroin initiation. Presentation at ONDCP Interagency Meeting on Heroin. June 28, 2012.

⁵ Substance Abuse and Mental Health Services Administration, Results from the 2011 National Survey on Drug Use and Health.

⁶ Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Full Report, Page 10.

⁷ Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

⁸ Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

⁹ Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

As one would expect, this abuse leads to increased diversion, and, in turn, increased enforcement activity. The National Forensic Laboratory Information System (NFLIS) collects results of drug chemistry analyses conducted by Federal, state, and local forensic laboratories across the country. As such, NFLIS can provide detailed analytical results of drugs seized by law enforcement, including trends in the diversion of pharmaceutical controlled substances into illegal markets. As of June 14, 2013, 47 state laboratory systems, 94 local laboratory systems, and one territorial laboratory system were participating in NFLIS. In 2010, approximately 1.7 million drug analysis records were reported to NFLIS. The increase in opiate pain medication analyses conducted by NFLIS-reporting laboratories from 2001 to 2010 is staggering: 322 percent for oxycodone; 240 percent for hydrocodone; and 253 percent for morphine.

Drug abuse is a problem that cannot be addressed through law enforcement action alone. We will never be able to "arrest our way" out of this problem. The Office of National Drug Control Policy's 2011 Prescription Drug Abuse Prevention Plan, a multi-pronged approach that includes education, monitoring, proper medication disposal, and enforcement is a science-based and practical way to address this national epidemic. One role of DEA, in addition to enforcing the Controlled Substances Act (CSA), is to educate the registrant population—including health care providers—on their obligations under the CSA, as well as to educate parents, community leaders and law enforcement personnel regarding diversion trends, the scope of the problem, and how to best address prescription drug diversion in communities throughout the United States.

One of the factors that contribute to the abuse of pharmaceutical controlled substances is the perception by some members of the public that it is safer to abuse prescription substances than to abuse illicit substances. Additionally, black-market sales for prescription controlled substances are typically at five to ten times the retail value. Profits generated from these street sales provide a strong incentive for continued diversion. Another factor that contributes to the increase of prescription drug diversion is the availability of these drugs in the household. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users for abuse, accidental ingestion, or illegal distribution for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for treatment. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to abuse medications. The 2012 PATS noted that 56 percent of teens indicated that it's easy to get prescription drugs from their parent's medicine cabinet and, in fact, 49 percent of parents say "anyone can access their medicine cabinet." Furthermore, the 2011 NSDUH indicates that 71 percent of individuals in 2010-2011 who used pain relievers nonmedically in the past year obtained them from a friend or relative. 11

DEA has responded to this problem by coordinating, every six months, National Prescription Drug Take-Back events with our Federal, state, local, and tribal law enforcement partners. Since September 2010, DEA has held six National Prescription Drug Take-Back Days, resulting in the collection of approximately 2.8 million pounds (1,409 tons) of unwanted prescription drugs. Removing household medication that is unwanted or no longer needed is a key component to limiting the availability of and access to these drugs by children and drug seekers for non-medical purposes. DEA is fully engaged in ensuring proper disposal of controlled substances and is

10 Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

¹¹ Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

currently finalizing regulations implementing the Secure and Responsible Drug Disposal Act of 2010, which authorizes additional ways for Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner.

Means by Which Pharmaceutical Controlled Substances Are Diverted

Understanding the means by which controlled substances are diverted is critical in determining appropriate regulatory controls. Diversion of pharmaceutical controlled substances can occur in a number of ways, including, but not limited to, the following:

- Prescription pads are stolen from practitioners' offices by patients, staff, or others, and illegitimate prescriptions are written and forged.
- Legitimate prescriptions are altered to obtain additional amounts of legitimately prescribed controlled substances.
- Drug-seeking patients may falsify symptoms or obtain multiple prescriptions from different practitioners for their own use or for resale. In some cases, organized groups visit practitioners with fake symptoms to obtain prescriptions, which are filled and resold. Some patients resell their legitimately obtained drugs to earn extra money.
- Prescription pads containing legitimate practitioner information (e.g., name, address, DEA registration number) are printed with a different call-back number that is answered by an accomplice to verify the prescription.
- Computers and scanning or copying equipment are used to create prescriptions for non-existent practitioners or to copy legitimate practitioners' prescriptions.
- Pharmacies and other locations where pharmaceutical controlled substances are stored are robbed or burglarized.

Diversion from within the practitioner's practice or pharmacy may also occur, such as in the following situations:

- Prescriptions are written for other than a legitimate medical purpose.
- Pharmaceutical controlled substances are stolen from pharmacies by pharmacy personnel. Legitimately dispensed prescriptions may be altered to make the thefts less detectable.
- Pharmacists are not exercising their coordinating responsibility to ensure that prescriptions are valid.

Recent Schemes to Divert Controlled Substances

Over the past several years, DEA Diversion Investigators and Special Agents have uncovered two types of illegal schemes used to divert powerful and addictive controlled substance pharmaceuticals. Florida was the epicenter of many illegal operations whereby hundreds of millions of dosage units of controlled substances were diverted into the illicit marketplace across the United States. Between 2005 and 2009, the diversion of millions of dosage units of Schedule III hydrocodone products was

facilitated by rogue internet pharmacies and unscrupulous prescribers who provided prescriptions to drug seekers utilizing these sites.

The Ryan Haight Online Pharmacy Consumer Protection Act that took effect in April 2009 responded to the explosion of domestic rogue internet pharmacy diversion. This law, combined with intensified law enforcement and regulatory actions, virtually eliminated domestic-based rogue internet pharmacies that were involved in internet controlled substance distribution. Internet traffickers have adapted to the law, for example by selling legend drugs and Fioricet (containing butalbital, a Schedule III controlled drug), which is exempt from administrative regulations but not criminal sanctions under the CSA.

As the number of domestic, internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics, particularly in Florida. Instead of hydrocodone, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a Schedule II controlled substance that is just as dangerous as hydrocodone when taken for a non-medical use. There was a sharp increase in pain clinics located in the tri-county area of South Florida (comprised of Broward, Miami-Dade, and Palm Beach Counties) in 2009. According to data provided by the State of Florida, by 2010, Broward County alone was home to approximately 142 rogue pain clinics. Federal, state and local law enforcement investigations identified thousands of drug seekers that routinely traveled to Florida-based rogue pain clinics to obtain pharmaceutical controlled and non-controlled substances, such as oxycodone, hydromorphone, methadone, tramadol, alprazolam, clonazepam, and carisoprodol. They then would travel back to their home states and illegally distribute the drugs that ultimately flooded the illicit market in states along the entire East Coast and the Midwest.

In response to this problem, state legislation in Florida was implemented to restrict a physician's ability to dispense oxycodone and other controlled substances from a pain clinic. However, dispensing controlled substances from these clinics was a huge source of income for clinic owners. Some clinic owners moved operations out of Florida to avoid increased law enforcement and regulatory pressure and the new legislation. Federal, state, and local law enforcement agencies have tracked the expansion of these clinics to other states, including Georgia, Tennessee, Ohio, Missouri, Texas, California, and Pennsylvania. Other rogue pain clinic owners and practitioners adapted to the new laws by issuing illegitimate prescriptions for oxycodone and other controlled substances rather than dispensing directly to the "customer." DEA and other law enforcement agencies saw an immediate and significant increase in the volume of oxycodone dispensed from various pharmacies across the State of Florida.

Seeing their profits going to dispensing pharmacies across the State, clinic owners began purchasing pharmacies and locating them at or near the pain clinics. The purchase of pharmacies is part of the scheme by rogue pain clinic owners to circumvent Florida laws: if a pain clinic cannot lawfully dispense drugs directly to a "customer," then the pain clinic will issue illegitimate prescriptions to "customers," and the pain clinic pharmacy will dispense drugs based on those illegitimate prescriptions. As a result of this scheme, there was a sharp increase in the number of new pharmacy registration applications in the State of Florida. The rise in the number of new pharmacy applications in Florida lead DEA to initiate on-site investigations of all pharmacy applications in Florida, ¹² rather than rely upon state licensure to ensure that the applicants have the requisite skill

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¹² On-site investigations of registrant applicants are conducted by DEA pursuant to its authority under 21 U.S.C. 822(f) and 21 CFR 1301.31.

and experience to safely and responsibly dispense controlled substances, sufficient knowledge of applicable federal law and regulations, and that the applicants intend to comply with Federal laws and regulations.

Further investigation of pharmacy applicants revealed "straw purchases" of pharmacies that had ties to established rogue pain clinics. During the on-site investigations, DEA personnel interviewed numerous applicants with backgrounds such as drywall installer, truck driver, bartender, lawn service owner, and spouse of a pain clinic owner. Many of the applicants had little or no experience with pharmacy operations. To date, this initiative has conducted five deployments to Florida. As a result, 132 retail pharmacies and one distributor have withdrawn their applications. The majority of these withdrawals, including the distributor application, were located in South Florida. As a result of this and other initiatives in Florida, 154 existing retail pharmacies have surrendered their registrations (again, the majority of which were in South Florida). Preventing these pharmacies from conducting business undoubtedly prevented millions of dosage units of controlled substances from entering the illicit market and closed an avenue of distribution and source of income for the rogue pain clinics. This initiative is on-going and has been expanded to other states where DEA has seen an unexplained increase in pharmacy applications.

DEA-registered pharmacies are generally supplied by DEA-registered wholesale distributors. Rogue pain clinics, pharmacies that fill illegitimate prescriptions for pain clinic "patients," and the wholesale distributors who supply these pharmacies have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted. Consequently, the registrants involved—practitioners, pharmacies, and wholesale distributors that do not comply with the CSA and its implementing regulations—are allowing millions of dosage units of controlled substances to pour into the illicit market, posing an imminent danger to the public health and safety. The damage to society is evident from the number of pharmaceutical overdose deaths reported recently by the Centers for Disease Control (CDC). CDC analysis revealed that 38,329 people died from a drug overdose in the United States in 2010. Nearly 60 percent of the drug overdose deaths (22,134) involved pharmaceutical drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were involved in about 3 of every 4 pharmaceutical overdose deaths (16,651), confirming the predominant role opioid analgesics play in drug overdose deaths.

Registration and Information Sharing

The level of control mandated by Congress for pharmaceutical controlled substances far exceeds that for other prescription drugs. This level of control is commensurate with the potential for physical and psychological dependence and abuse properties associated with controlled substances and is necessary to help prevent abuse and diversion of these substances.

One of the most effective tools to ensure legitimate use of pharmaceutical controlled substances is the registration requirement. The following individuals and entities are required to be registered with DEA: any business that imports or exports a controlled substance, or that manufactures or distributes a controlled substance; pharmacies that dispense controlled substances; practitioners that prescribe, administer, or dispense controlled substances; and any person that conducts research or chemical analysis with a controlled substance. Currently, there are more than 1.4 million registrants registered with DEA, and the vast majority are practitioners (i.e., registered medical professionals

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¹³ Centers for Disease Control and Prevention, Press Release "Opioids drive continued increase in drug overdose deaths." (Feb. 20, 2013).

who prescribe, administer, or dispense pharmaceutical controlled substances). Once registered, each individual or business is issued a unique DEA registration number. DEA maintains over 2 million registration records in a database that includes historical and current regulatory action(s) taken against a registrant.

DEA provides an electronic means by which registrants can check the validity of another registrant's DEA registration number free of charge. DEA also provides access to state agencies that have a responsibility to investigate health care fraud. DEA provides daily access to the registrant database to 41 states, Guam, and D.C., which have requested the data. DEA provides this data to agencies such as the New York State Medicaid Inspector General's Office; the Illinois Office of Inspector General Health and Family Services the Illinois Department of Human Services Bureau of Pharmacy and Clinical Support Services; the North Carolina Medical Board; and the Texas Department of Public Safety, Controlled Substances Registration section. Additionally, DEA provides a listing of current DEA registration numbers to the National Technical Information Service (NTIS), an agency of the U.S. Department of Commerce, on a weekly basis. NTIS collects and disseminates technical information produced by and for Federal agencies. It operates on a self-sustaining basis and makes this information widely available to those who need it on a subscription basis at no cost to the Treasury. DEA currently receives the Social Security Death Master List, and cross-checks that information with DEA registration records to better reconcile these two databases and thereby curb potential avenues of healthcare fraud.

The CSA and DEA Regulations Pertaining to Prescriptions for Controlled Substances

In enacting the CSA, Congress sought to control the diversion of pharmaceutical controlled substances into illicit markets by establishing a closed system of distribution for controlled substances. The CSA requires that a prescription for a controlled substance may be issued only by a practitioner who is registered with DEA, or exempt from registration, and who is also authorized to prescribe controlled substances by the state in which they are prescribing. The CSA and its implementing regulations help maintain the integrity of this closed system of distribution by requiring registrants to adhere to specified security, recordkeeping, and reporting requirements, as well as controlling and limiting legitimate transfers of controlled substances by and between specified registrants. When DEA registrants adhere to the CSA and its implementing regulations, diversion of pharmaceutical controlled substances from the closed system of distribution is prevented.

The closed system is specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain as well as the registrants within the health care delivery system. All registrants must adhere to specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion. Adherence to these requirements at every level of the delivery and supply chain will reduce the opportunities for diversion.

Practitioners, such as prescribers and pharmacists, must adhere to additional requirements when prescribing or dispensing controlled substances. For example, an individual practitioner such as a physician, dentist, veterinarian, or mid-level practitioner may only dispense or prescribe a controlled substance for a legitimate medical purpose while acting in the usual course of professional practice. 21 CFR §1306.04(a); *United States v. Moore*, 423 US 122 (1975). While the vast majority of practitioners act in accordance with the law, requirements such as this are disregarded at rogue pain

clinics operating throughout the United States. Rather than providing medical care, they utilize the façade of medical care as a front for illegal controlled substance distribution activities. The "physicians" that operate in rogue pain clinics are feeding the addiction of drug seekers. These clinics have minimal physician-patient interaction and generally provide the medication requested by the patient (patient-directed prescribing) without question. There is no attempt to determine the underlying cause of pain and the standard accepted medical practice is disregarded. Most of the practitioners that write prescriptions in these facilities are committing criminal and civil violations of the CSA. If the practitioners in these clinics were to abide by the requirement to issue a prescription only for a legitimate medical purpose and in the usual course of professional practice, drug seekers would not have the opportunity to feed their addiction or to distribute pharmaceutical controlled substances into the illicit market.

A legitimate prescription may be filled only by a pharmacist acting in the usual course of professional practice who is employed in a DEA-registered pharmacy. Except under limited circumstances, a pharmacist may dispense a schedule II controlled substance only upon receipt of a valid electronic prescription or an original written prescription manually signed by the practitioner. A pharmacist may dispense a schedule III or IV controlled substance only pursuant to a legitimate oral, written, or electronic prescription from an individual practitioner. The elements of a prescription that identify the practitioner (i.e., the practitioner's name, address, DEA registration number, and signature) also serve to enable a pharmacy to authenticate the prescription. If a pharmacy is unfamiliar with the practitioner identified on the prescription, it can use the registration number to verify the identity and prescriptive authority of the practitioner.

Ultimately, the last line of defense against diversion is the pharmacist that receives the prescription for medication dispensing. The pharmacist is obligated to ensure that a prescription for a controlled substance is legitimate before dispensing the medication to the patient. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription . . . and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR §1306.04(a). The pharmacist is the "drug expert" in the healthcare delivery system and is well equipped to review a prescription to determine if it is legitimate. If more pharmacists questioned the validity of prescriptions issued by rogue pain clinic physicians and refused to fill the prescriptions based upon their professional judgment, diversion would be significantly decreased. The exercise of their "corresponding responsibility," in many instances, is an opportunity for pharmacists to save lives.

DEA regulations require registered pharmacies to maintain records of dispensing activities for two years from the date of dispensing of the controlled substance. However, some states require that these records be maintained for longer periods of time. These records must be made available for inspection and copying by authorized employees of DEA. This system of records is unique in that the prescribing practitioner creates the prescription, but the dispensing pharmacy retains the prescription as a record of dispensing. DEA does not have authority to require pharmacies to report their controlled substance dispensing activities to DEA. However, DEA does have an administrative authority to access these records stemming from the authority to inspect registered premises.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are typically electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMP programs and encourages the use of these programs by medical professionals in detecting and preventing doctor shopping and other forms of diversion. Currently, 46 states have an operational PDMP; 3 more states have enacted PDMP legislation, but do not have operations programs; and 1 state (Missouri) and the District of Columbia do not have legislation. Additionally, DEA makes its registrant database available to any state, without a fee, for use in their PDMP or other state agency charged with investigating health care fraud or controlled substance diversion. These programs, however, are only as good as the data that is in each system and the willingness of practitioners and pharmacists to use such systems on a consistent basis.

Medicare and Medicaid Fraud

Federal investigations of health care fraud are conducted pursuant to the authority of Title 18 U.S.C. §§ 287 and 1001, 18 U.S.C. § 1347, 18 U.S.C. §1518 and Title 42 U.S.C. § 1320a-7b. State agencies also have authority to investigate Medicaid fraud within their jurisdictions. While these violations are outside DEA's jurisdiction, there are occasions when, while investigating violations of the Controlled Substances Act, DEA agents and investigators uncover violations involving health care fraud. This information is shared with investigators from the Department of Health and Human Services (HHS), the Federal Bureau of Investigation (FBI), and other investigative agencies with relevant Federal or state authorities.

The importance of these cooperative and information sharing relationships are reflected in the fact that HHS Office of the Inspector General, the FBI, and others have investigators assigned or are working on an ad-hoc basis with some of our Tactical Diversion Squads. This expertise and contact facilitates information sharing between all of the involved agencies, and allows investigators to easily draw upon each other's expertise when conducting an investigation.

The Drug Enforcement Administration Response to the Prescription Drug Abuse Crisis

Just as illicit drug traffickers and organizations adapt to law enforcement methods, pharmaceutical traffickers adapt to and circumvent laws that attempt to stop the flow of controlled substance pharmaceuticals into the illicit market. As such, law enforcement efforts to prevent, detect, and reduce the diversion of controlled substance pharmaceuticals continue to evolve. DEA has taken action on several fronts over the past few years to help reduce this growing problem.

Restructuring

In October 2008, the then-Acting Administrator authorized a two-pronged reorganization of the Diversion Control Program. The first prong involved a substantial expansion in the number of Tactical Diversion Squads (TDSs) and their deployment throughout the United States. This approach provided a significant increase in the number of Special Agents and Task Force Officers who possess the requisite law enforcement authorities needed when conducting criminal investigations, i.e., the ability to conduct surveillance, make undercover purchases, make arrests, and execute search warrants. The second prong of the reorganization plan called for a renewed

focus on DEA's regulatory oversight of more than 1.4 million DEA registrants. With more Diversion Investigators available to concentrate on the regulatory aspects of the Diversion Control Program, DEA increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; importers; exporters; narcotic treatment programs; practitioners waived under the Drug Addiction Treatment Act to prescribe certain controlled substances to treat opioid addiction and dependence without obtaining a separate registration to do so; researchers; and chemical handlers. This renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the Controlled Substances Act and its implementing regulations.

Expansion of Tactical Diversion Squads

Tactical Diversion Squads (TDS) investigate suspected violations of the CSA and other Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shopping," prescription forgery rings, and practitioners or pharmacists who divert controlled substance pharmaceuticals).

As of June 14, 2013, 66 TDS groups have been approved throughout the United States, of which 51 are operational. With the expansion of TDS groups across the U.S., the number of diversion-related criminal and administrative cases has increased significantly. For example, between fiscal year (FY) 2008 and FY 2012, regulatory inspections increased from 1,192 to 4,675 (a 392% increase). Between FY 2008 and FY 2011, administrative actions, including Orders To Show Cause and Immediate Suspension Orders, increased from 70 to 131 (a 87% increase). An Order To Show Cause, which commences administrative action against a registrant, is an order from DEA that provides notice to a registrant that the registrant may show cause, at an administrative hearing or through submission of documentary evidence, as to why the DEA should not revoke their registration or deny their application for a DEA registration on the basis of any of the enumerated statutory factors. An Immediate Suspension Order is an administrative action in which the DEA Administrator simultaneously suspends the registrant's DEA registration with the commencement of Order to Show Cause proceedings because their continued registration pending the administrative proceeding would pose an imminent danger to the public health or safety.

Between FY 2008 and FY 2013 as of June 13, 2013, these TDS groups have also increased the number of diversion-related Priority Target Organization (PTO) investigations from 243 to 595 (a 141% increase). PTO investigations focus on those criminal organizations or groups that significantly impact areas of the country. On October 1, 2011, DEA began tracking non-criminal PTO investigations, which encompass regulatory, civil, and administrative investigations. Since then, there have been 75 designated non-criminal PTO investigations.

The restructuring of the Diversion Control Program has allowed investigative efforts to focus on specific problem areas. For example, DEA, working with its state and local partners, put forth a substantial investigative effort towards rogue clinics, dubbed *Operation Pill Nation I*. This operation involved the mobilization of eleven TDSs from across the United States to marshal with the Miami TDS and other state and local agencies in a concerted effort to attack and dismantle the hundreds of rogue pain clinics that continued to plague South Florida. On February 23, 2011, DEA,

as part of *Operation Pill Nation I*, conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown. As of June 14, 2013, *Operation Pill Nation I* resulted in 47 arrests, including 27 doctors; the issuance of 34 Immediate Suspension Orders against 63 DEA registrations; 92 DEA registrations being surrendered for cause; and the seizure of more than \$18.9 million in assets.

DEA conducted a similar operation in the central Florida area, dubbed *Operation Pill Nation II*. As of June 6, 2013, *Operation Pill Nation II* has resulted in 58 arrests, including 9 doctors and 4 pharmacists; the issuance of 4 Immediate Suspension Orders; 7 DEA registrations being surrendered for cause; and the seizure of approximately \$311,995 in assets.

Renewed Oversight

DEA uses its regulatory authority to ensure that DEA registrants comply with all aspects of the CSA and its implementing regulations, particularly maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. One way DEA attempts to accomplish this is through our Distributor Initiative Program. This program was implemented in late 2005 and is designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to rogue pain clinics and rogue pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes. As stated above, wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA educates distributors about their obligations under the CSA, as well as provides registrants with current trends and "red flags" that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer.

DEA vigorously pursues criminal, administrative, and civil actions against registrants who fail to comply with all aspect of the CSA and its implementing regulations as required. DEA has identified various distributors who failed to adhere to their regulatory responsibilities to maintain effective controls against diversion, resulting in administrative action and referral for civil action. These investigations resulted in record-breaking civil penalties (\$13.25 million against McKesson Drug Corporation in April 2008 and \$34 million against Cardinal Health in October 2008). More recent examples include, but are not limited to, actions against wholesale distributors such as Harvard Drugs, Keysource, and Sunrise.

In February 2012, the DEA Administrator again used her authority under the CSA to immediately suspend the registrations of Cardinal Health's Lakeland, Florida, facility and two Sanford, Florida-based CVS pharmacies (stores 219 and 5195) after making a determination that the continued operation of these facilities (with respect to controlled substances), while pending administrative proceedings to revoke their registrations posed an imminent danger to the public health or safety. A Memorandum of Agreement has been reached between DEA and Cardinal Health regarding their conduct, which includes a suspension of their Lakeland facility registration for a period of two years. On August 31, 2012, the DEA Administrator issued a Final Order revoking the registrations of both of the CVS pharmacies.

On March 29, 2013, as a result of an eight-year investigation of illegal Internet pharmacies, United Parcel Service, Inc. (UPS) agreed to forfeit \$40 million, which was alleged to be the profits earned

from conducting business with illegal Internet pharmacies, to the U.S. Government and entered into a non-prosecution agreement. This agreement requires the world's largest package delivery company to implement a comprehensive compliance program prohibiting illegal Internet pharmacies from using their services.

On June 11, 2013, Walgreens Corporation, the nation's largest drug store chain, agreed to pay \$80 million in civil penalties, resolving DEA's administrative actions and a civil penalty investigation by the United States Attorney's Office regarding the Jupiter Distribution Center and six retail pharmacies in Florida. The settlement, the largest in DEA history, resolved the allegations that Walgreens committed an unprecedented number of record-keeping and dispensing violations under the Controlled Substances Act. The Settlement and Memorandum of Agreement also includes the suspension of the Jupiter Distribution Center registration until September 14, 2014, and the registrations of the six pharmacies until May 26, 2014.

Education

DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country; to date, 16 separate PDACs have been held in 8 states. Each one-day conference is held on a Saturday or a Sunday for the convenience of the pharmacy community. The conference is designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of this conference is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. In addition, since FY 2012, the Office of Diversion Control has separately conducted more than 100 presentations to the public, educators, community-based organizations, registrants, and their professional organizations, industry organizations, and law enforcement agencies regarding the diversion and abuse of pharmaceutical controlled substances.

Conclusion

Minimizing the availability of pharmaceutical controlled substances to non-medical users and maintaining the integrity of the closed-system of distribution are priorities for the Drug Enforcement Administration. As such, DEA will continue to work in a cooperative effort with other Federal, state, and local officials, law enforcement, professional organizations, and community groups to address this epidemic.